Inventor: PICKFORD ET AL
Serial No.: 10/501,538
Filing Date: 7/16/2004
Examiner: Thomas C. Barrett
Group Art Unit: 3738

REMARKS

The Office Action of September 21, 2006 has been carefully considered and the application has been amended accordingly.

Claims 20-40 are present in the application. Independent claims 20, 26 and 32 have been amended, and new claims 38, 39 and 40 have been added to further define applicants' invention. Claims 26 and 32 have been amended to overcome the rejection based upon Section 112.

Parent claims 20, 26 and 32 have been amended to more particularly define Applicants' implant wherein, "the quantity of biocidal metal ions being such that the biocidal material is effective in suppressing infection after the surgical procedure." This amendment clarifies that the whole point of the present invention is to introduce a biocidal material so as to suppress or control infection. While this aspect is implicit already, the amendment states it explicitly. This additional limitation is based on page 1 lines 5-6; page 2 lines 9-12 and page 5 lines 18-23.

New claims 38, 39 and 40 depend, respectively, from independent claims 20, 26 and 32 and further specify that "the biocidal material adsorbed into said surface layer is effective in suppressing infection for at least 6 weeks after the surgical procedure." This limitation is clearly based on page 2 lines 9-10.

The Examiner has withdrawn previous rejections based upon Ogle (U.S. patent 6,113,636.)

Claims 20-37, as previously presented, have been rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg *et al.*

This citation does indeed have some superficial similarities, as it relates to a process in which a device (which may be a titanium alloy prosthetic device or implant) is subjected to an anodizing procedure using phosphoric acid. The aim of the procedure is however very different, as the intention is to achieve an oxide coating of good dielectric strength, to improve corrosion resistance and to reduce ion release rates as is clear from column 3, line 34 and column 5, line 16 (this is clearly different from Applicants' recited biocidal aspect); and the process for making the coating is also significantly different in that it requires a substantially non-aqueous organic solvent for the anodizing step.

However, as the examiner pointed out, in Rosenberg's process - as an option - "silver nitrate is then added to the solution" that contains phosphoric acid. The silver nitrate, in Rosenberg's process, is added in very small amounts to the anodizing solution (the phosphoric acid solution), just enough to precipitate any chloride ions (which will form a white precipitate of silver chloride). If a slight excess of silver ions are added there will be a yellow precipitate of silver phosphate. It is a feature of Rosenberg's process that this silver phosphate is in the form of small particles which precipitate out from the anodizing solution. They do not form part of the surface coating on the metal product, thereby resulting in an article that is not comparable with Applicants' claimed implant.

Applicants respectfully submit that it will thus be appreciated that in Rosenberg's method there will be a very small concentration of silver ions present in the anodizing solution (because silver phosphate is substantially insoluble), but a much larger concentration of phosphoric acid and so of hydrogen ions. With aqueous phosphoric acid the hydrogen ion concentration would

be about 3000 times greater than the silver ion concentration; even with Rosenberg's partly organic solvent the hydrogen ion concentration is significantly higher than that of the silver ions - say at least 500 times. Since ion exchange depends on the concentrations of the cations present, very little silver will be adsorbed by ion exchange into the titanium oxide/titanium phosphate anodized coating because there is a large excess of hydrogen ions. Indeed acids are commonly used to elute cations from ion exchangers.

In contrast, in the present invention, the anodizing step is carried out using phosphoric acid; and the implant is then rinsed to remove phosphoric acid. The implant is then subjected to ion exchange in 0.1 M aqueous silver nitrate solution. In this case the ratio of the silver ion concentration to the hydrogen ion concentration is about 1000000:1. So comparing the two processes, the process of the present invention can be expected to provide about 500,000,000 times greater concentration of silver ions absorbed by ion exchange into the anodized coating.

It is therefore clear that Rosenberg's process does not produce implants with any significant level of silver ions incorporated by ion exchange, and therefore does not produce an implant with biocidal effects as now defined by amended parent claims 20, 26 and 32. Indeed Rosenberg had no intention of introducing any silver ions into his surface coating. In contrast, Applicants' claimed implant inherently provides a vastly greater concentration of silver ions adsorbed by ion exchange - about 500,000,000 times greater - and consequently a satisfactory biocidal effect after surgery. The very meaningful differences between Rosenberg's product and Applicants' novel implant is readily obvious to one of ordinary skill in the art upon inspection and comparison of the respective articles.

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In view of the foregoing amendments and remarks, reconsideration of the application is requested and allowance of claims 20-40 is courteously solicited.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted by facsimile this day to Examiner Thomas Barrett at the United States Patent and Trademark Office, Art Unit 3738, to fax No. 571-273-8300.

December 18, 2006 W. H. Holt
Signature